United States Court of Appeals

for the Second Circuit

BRIEF FOR APPELLEE

Orig. w/affidavit of mailing

76-6169

To be argued by
DAVID W. McMORROW

United States Court of Appeals

FOR THE SECOND CIRCUIT

Docket No. 76-6169

B
P/S

UNITED STATES OF AMERICA,
Plaintiff-Appellee,

—against—

NOVA SCOTIA FOOD PRODUCTS CORP.,
DAVID SKLAR and EMANUEL SKLAR,
Defendants-Appellants,

—and—

NATIONAL FISHERIES INSTITUTE,
Intervenor-Appellant.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

BRIEF FOR PLAINTIFF-APPELLEE

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Counterstatement of the Issues Presented

1. Whether the district court erred in holding that the time-temperature-salinity requirements of the current good manufacturing practice ("GMP") regulations promulgated by the Food and Drug Administration ("FDA"), 21 CFR 128a.7(d)(2), (c)(4), are within the scope of Section 402(a)(4) of the Food, Drug and Cosmetic Act (the "Act"), 21 U.S.C. § 342(a)(4).

2. Whether the district court erred in holding that the administrative record of the rulemaking proceeding demonstrates that the time-temperature-salinity requirements of the smoked fish GMP regulations are not "arbi-

trary, capricious, an abuse of discretion, or otherwise not in accordance with law," within the meaning of 5 U.S.C. § 706(2)(A).

3. Whether the district court erred in holding that the time-temperature-salinity requirements of the smoked fish GMP regulations are binding on appellants.

4. Whether the district court abused its discretion in granting injunctive relief.

Preliminary Statement

Nova Scotia Food Products Corp., David Sklar, the firm's president, and Emanuel Sklar, its vice-president and treasurer, appeal from a final judgment (A-804-809)[1] entered on October 18, 1976, by the United States District Court for the Eastern District of New York (Dooling, *J.*), enjoining them from violating certain provisions of FDA good manufacturing practice regulations in the production of hot-process smoked whitefish.[2] The district court, following a non-jury trial on May 17, 18 and 19, 1976, rendered a written opinion reported at 417 F. Supp. 1364 (E.D.N.Y. 1976) (A-723-776).

Statement of the Case

This civil action for injunctive relief, under Section 302(a) of the Act, 21 U.S.C. 332(a), was filed on April 7, 1976, to restrain Nova Scotia's[3] production of hot-

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[1] References preceded by the letter "A" are to the Joint Appendix.

[2] Although the National Fisheries Institute ("NFI"), intervenor-defendant below, also appeals from the district court's final judgment, that judgment does not enjoin any NFI activities.

[3] Defendants-appellants and intervenor-appellant, unless otherwise indicated, will be referred to herein as "Nova Scotia."

process smoked fish (with the exception of chubs) which were adulterated within the meaning of Section 402(a)(4) of the Act, 21 U.S.C. 342(a)(4).[4] The Government alleged that such fish were adulterated within the meaning of Section 402(a)(4) in that the facilities, methods, practices and controls used by Nova Scotia in the manufacture, processing, packing and holding of such fish did not conform to and were not operated and administered in conformity with current good manufacturing practice in manufacturing, processing, packing and holding smoked fish, as prescribed by FDA regulations, 21 CFR Part 128a, Subpart A, to assure that such fish may not have been rendered injurious to health. Complaint ¶ 6 (A-5).

The smoked fish GMP regulations—promulgated on November 13, 1970—establish processing requirements designed to minimize the possibility of botulism poisoning to the consuming public. (A-757-758). Botulism food poisoning is caused by the lethal toxin produced by *Clostridium botulinum* type E organisms, spore-forming bacteria which are present in the soil and water of various regions. (A-170). These bacteria invade the fish in their natural habitat and are further disseminated in the course of evisceration and other preparation of the fish for cooking. (A-740-741). If the brining, cooking and refrigeration of smoked fish are inadequate, a lethal toxin may develop from viable *C. botulinum* type E spores and vegetative cells. (A-743-744).

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[4] Nova Scotia was charged with violating Section 301(k) of the Act, 21 U.S.C. 331(k), which prohibits, *inter alia*, "the doing of any . . . act with respect to, a food . . . if such act is done while such article is held for sale . . . after shipment in interstate commerce and results in such article being adulterated . . ." Complaint ¶ 10 (A-8).

The smoked fish GMP regulations require, among other things, that the temperature of the brine and the fish therein be at or below 38°F within 12 hours after the brining operation begins [21 CFR 128a.7(c)(3)]; that ovens used for cooking fish be equipped with a point-sensitive, continuous temperature recording device to monitor the internal temperature of the fish and the ambient temperature within the oven [21 CFR 128a.7(d)(1)]; that hot-processed smoked fish be cooked to reach an internal temperature throughout each fish of 180°F for a minimum of 30 minutes if the fish have been brined to contain 3.5 percent water phase salt [21 CFR 128a.7(d)(2)(i)], or, *in the alternative*, that hot-processed smoked fish be cooked to reach an internal temperature throughout each fish of 150°F for a minimum of 30 minutes if the fish have been brined to contain 5.0 percent water phase salt [21 CFR 128a.7(d)(2)(ii)]; and, that smoked fish be cooled to reach a temperature of 38°F within 12 hours after cooking [21 CFR 218a.7(e)(3)]. The alternative brining and cooking regulations—referred to as the time-temperature-salinity requirements—are the focal point of this litigation.

The Government established at trial that, with respect to whitefish,[5] Nova Scotia failed to comply with the GMP regulations, notably the time-temperature-salinity requirements. (A-724). Indeed, Nova Scotia conceded its violation of the time-temperature-salinity requirements. (A-729). It sought to justify non-compliance by asserting that these requirements could not be met if a marketable whitefish was to be produced. *Id.*

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[5] It should be noted that only 40% of the fish processed by Nova Scotia are hot-smoked and thus subject to the GMP regulations. (Govt. Ex. 6;A-786). And, only 10% of Nova Scotia's hot-smoked fish are whitefish. *Id.*

In an attempt to establish that it was impossible to comply with the time-temperature-salinity requirements and still yield a commercially acceptable product, Nova Scotia called several smoked fish processors who offered their opinions on the subject. (A-277, *et seq.*). Nova Scotia also called three witnesses as part of a "taste test" involving what it claimed was a comparison of the commercial acceptability of whitefish purportedly prepared in compliance with the regulations with those purportedly prepared in its normal fashion. (A-405 *et seq.*). The district court, however, found that, even assuming this evidence to be relevant,[6] Nova Scotia failed to show that a marketable could not be produced. (A-771-774). Thus, Nova Scotia's repeated references in its "Statement of the Case" [Br. pp. 2-9] [7] to the impossibility of complying with the regulations and still producing a marketable product are distinctly contrary to the trial court's findings.

The district court also considered and rejected Nova Scotia's multifaceted attack on the validity of the time-temperature-salinity requirements (A-729). It held: (1) that the regulations were within the scope of Section 402(a)(4) of the Act (A-731-737); (2) that the regulations—promulgated under the general rulemaking authority in Section 701(a) of the Act, 21 U.S.C. 371(a)—constitute binding legal requirements, the violation of which renders smoked fish adulterated within the mean-

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[6] The court observed that:

> [E]ven if such a proposition could be demonstrated, it is not an answer to the regulation to say that marketable fish could not be processed under it. If that were the case it would simply mean that smoked whitefish cannot be processed in their only marketable form without an unacceptable threat to public health. (A-773).

[7] References to "Br." are to Nova Scotia's Brief on appeal.

ing of Section 402(a)(4) (A-737-739); (3) that FDA validly concluded that a reasonable possibility of injury to health from *C. botulinum* type E may arise in the absence of strict time-temperature-salinity processing controls (A-739-747); (4) that the administrative record of the GMP regulations, whether it be construed as containing all the scientific materials contended for by the Government or whether, as Nova Scotia urged, it be limited to the materials on file with the FDA Hearing Clerk, supported the validity of the time-temperature-salinity requirements (A-747-771); and (5) that even considering the evidence offered by Nova Scotia in its attempt collaterally to attack the validity of the time-temperature-salinity requirements *de novo*, the regulations were nonetheless valid (A-775-776).

Following the submission of proposed judgments by the Government and Nova Scotia (A-795-799, 779-781), the district court, on October 18, 1976, entered its own decree. (A-804-810). Although the Government sought injunctive relief covering all GMP violations occurring in Nova Scotia's production of any specie of hot-smoked fish (except chubs), whitefish was the single specie whose violative production was enjoined and then only insofar as requiring compliance with the time-temperature-salinity requirements. Concurrent with the entry of its final judgment, the district court denied Nova Scotia's motion for a stay thereof pending appeal. (A-811).[8]

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[8] This order also denied Nova Scotia's request for a deferred effective date of the judgment, the Court noting that the judgment as approved had a somewhat deferred effective date (60 days before compliance with time-temperature-salinity requirements was mandated).

ARGUMENT

POINT I

The Time-Temperature-Salinity Requirements of the Smoked Fish GMP Regulations Do Not Exceed The Scope Of Section 402(a)(4) of the Act.

The smoked fish GMP regulations were promulgated by the Commissioner of Food and Drugs pursuant to his general rulemaking authority under Section 701(a) of the Act, 21 U.S.C. 371(a).[9] They were intended specifically to particularize Section 402(a)(4) of the Act, 21 U.S.C. 342(a)(4), which provides that food shall be deemed to be "adulterated"

> if it has been prepared, packed or held under insanitary conditions [1] whereby it may have become contaminated with filth, or [2] whereby it may have been rendered injurious to health.

The failure to process hot smoked fish in accordance with the GMP requirements so as to prevent the possible outgrowth and toxin formation of *C. bolulinum* type E bacteria constitutes an insanitary condition which may result in the final product being contaminated or injurious to the health of the consuming public.

Nova Scotia argues that because *C. botulinum* type E bacteria are organisms absorbed by whitefish in their natural environment (A-740), and not as a result of dirt

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[9] Under Section 701(a), the Secretary of H.E.W. has the authority "to promulgate regulations for the efficient enforcement of [the] Act." The Secretary has delegated his authority under the Act to the Commissioner. 21 CFR 5.1(a). [formerly 21 CFR 2.120(a)(1), recodified at 41 Fed. Reg. 24262 (June 15, 1976)].

or filth at the smoked fish processing plant, their presence or absence in the final product is totally unconnected with "insanitary conditions" as that term is conventionally used. [Br. p. 10]. Thus, it maintains, the time-temperature-salinity requirements of the GMP's [10] are unrelated to, and exceed the substantive scope of Section 402(a)(4).[11] This argument is without merit.

Nova Scotia cites numerous cases [Br. pp. 16-17] for the proposition that adulteration within the meaning of this section necessarily requires the presence of traditional indicia of "filth." Thus, it argues, regulations particularizing this section are properly limited to situations associated with such "filth." The cited cases, however, illustrate only that the presence of rodents, flies, insects and the like constitute insanitary conditions under Section 402(a)(4). They in no way establish that the scope of Section 402(a)(4) is limited exclusively to such conventional varieties of "filth." If that were the case, then the second clause of the section would be superfluous.

Moreover, Nova Scotia's argument that Section 402(a)(4) is limited in scope is contradicted by the terms of the statutory provision itself. While the first clause applies to filth which may not necessarily endanger

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[10] These requirements are specifically designed to destroy a certain number of *C. botulinum* type E spores, to heat damage others, and to inhibit the outgrowth of surviving spores and thus, preclude development of their lethal toxin. (A-735). The regulations also contain provisions respecting plants and grounds, equipment and utensils, and sanitary facilities, controls and operations. 21 CFR 128a.3 through 128a.6. (A-618-619).

[11] The Government agrees with Nova Scotia that any regulation which goes beyond its statutory predicate is invalid. See Br. pp. 21-23. As demonstrated herein, however, the time-temperature-salinity requirements of the smoked fish GMP regulations are well within the ambit of Section 402(a)(4).

health, the second clause is directed toward those insanitary conditions of whatever nature which may render food injurious to health. It is a well-settled rule of statutory construction that a court "should prefer a construction of the statute which leaves to each element of the statute a function in some way different from the others." *United States* v. *Dinnerstein*, 362 F.2d 852, 855-856 (2d Cir. 1966).[12]

While the cases cited by Nova Scotia may be illustrative of actions brought by FDA to enforce Section 402 (a)(4), they are largely irrelevant to consideration of the agency's attempt, via the time-temperature-salinity requirements, to particularize the Act's requirements through rulemaking. Such rulemaking, the courts have declared, is the "preferred procedure," *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 620 (1973); *Ciba-Geigy Corp.* v. *Richardson*, 446 F.2d 466, 468 (2d Cir. 1971), for implementation of general statutory standards.

More directly in point is the recent decision in *Federation of Homemakers* v. *Schmidt*, 539 F.2d 740

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[12] *See e.g. United States* v. *484 Bags, More or Less*, 423 F.2d 839, 840 (5th Cir. 1970) (decision construing the two clauses of Section 402(a)(3) of the Act, 21 U.S.C. 342(a)(3), as "independent and complimentary, so that a food substance may be condemned as decomposed, filthy, or putrid even though it is not unfit for food . . . or condemned as unfit for food even though not decomposed filthy, or putrid"); *See also e.g. United States* v. *449 Cases . . .*, 212 F.2d 567 (2d Cir. 1954); *Bruce's Juices* v. *United States*, 149 F.2d 935 (5th Cir. 1952); *Salamonie Packing Co.* v. *United States*, 165 F.2d 205 (8th Cir.), *cert. denied*, 333 U.S. 863 (1948); *United States* v. *1851 Cartons . . .*, 146 F.2d 760 (10th Cir. 1945); *United States* v. *Frigid Food Product, Inc.*, 339 F. Supp. 131 (N.D. Ga., 1972); *United States* v. *Capital City Foods, Inc.*, 345 F. Supp. 277 (D. N.D. 1972); *United States* v. *24 Cases . . .*, 87 F. Supp. 826 (D. Me. 1949).

(D.C. Cir. 1976), where the court upheld FDA's definition of a statutory term not defined by the Act, even though the precise definition prescribed by regulation had not been judicially articulated in enforcement cases. The court observed that "[w]hile it is true that these judicial definitions may be reasonable ones, we do not believe that they prevent the promulgation of any equally reasonable definition by the agency charged with administering the Act." 539 F.2d at 743. *Accord, American Frozen Food Institute* v. *Mathews*, 412 F. Supp. 548 (D.D.C. 1976), *appeal docketed*, No. 76-1620, D.C. Cir., June 1, 1976.

The district court correctly understood that although "the bacterial infestation here is not one that invades the fish during the processing," (A-736), the failure adequately to heat and brine the fish so as to prevent the outgrowth and toxin formation of *C. botulinum* type E is an "insanitary condition" which may render the fish injurious to health. As the court observed in discussing Section 402(a)(4),

> [I]t evinces a manifest and dominant purpose to deal with the cases in which the food has been prepared, packed or held under conditions whereby it *may have* become contaminated with filth or *may have* been rendered injurious to health. (Emphasis in original). *Describing the manufacturing condition as "insanitary" is secondary: the the word is given operative content only by reference to the purpose of subsection (a)(4), that is, to provide against whatever condition of processing may render the product injurious to health or contaminate it with filth.* (Emphasis supplied).
>
> Only subdivision (4) of [21 U.S.C.] Section 342 (a) treats a food as adulterated whether or not the food has in fact been contaminated or rendered

> injurious to health. Food is considered adulterated if it has been prepared, packed or held under conditions that *may have* resulted in its contamination or in its becoming injurious to health. It is the only one of the subdivisions which directly deals with processing rather than with product in defining the circumstances in which the food product will be considered adulterated. For purposes of subdivision (4), it is irrelevant that, by any other tests, the food could not have been condemned. While Section 342(a)(4) may literally seem to deal only with conditions brought about by processing itself, the regulation under review, Part 128a, is specifically addressed to setting processing parameters to prevent the "outgrowth and toxin formation of C. botulinum Type E." *Seen in the perspective of Part 128a's purpose and the purpose of subsection (a)(4), the use of the word "insanitary" in subdivision (4) of Section 342(a) is, at worst, inelegant, but it is not inadequate to include preparing, packing or holding conditions which permit a continuance of the outgrowth and toxin formation of the C. botulinum Type E in the product under process.* (Emphasis supplied). (A-733-734).

Thus, it is not the nature of the contaminant, but its potential effect that determines whether the failure adequately to heat and brine smoked whitefish constitutes an insanitary condition whereby the fish may have been rendered injurious to health and, therefore, whether the time-temperature-salinity requirements are within the scope of Section 402(a)(4).

This construction of Section 402(a)(4) is supported by the recent decision in *National Confectioners Association* v. *Mathews*, F. D. Cosm. L. Rep. ¶ 38,062 (D.D.C.

April 14, 1976), *appeal docketed*, No. 76-1617, D.C. Cir., July 14, 1976. In that case, FDA had promulgated Good Manufacturing Practice regulations under Section 701(a) of the Act which, like those in the instant case, particularized certain requirements under Section 402(a)(4). Specifically, the regulations required product coding and record keeping in order to facilitate, if necessary, a recall of food adulterated with microbiological or other contaminants.[13] The regulations, therefore, were directly related to protection of the public health. The time-temperature-salinity requirements here at issue have an even more direct relation to the protection of the public health because they are designed to prevent, in the first instance, the production of smoked fish adulterated with *C. botulinum* type E bacteria which, if left untreated, may produce their lethal toxin.

Plaintiffs in *National Confectioners* argued that the GMP regulations exceeded FDA's statutory authority under the Act. The Court squarely rejected the contention, holding that "[t]he statutory scheme as a whole and §§ 402(a)(4) and 701(a) in particular clearly provide an adequate statutory basis for the promulgation of the regulations." F. D. Cosm. L. Rep. ¶ 38,062 at p. 38,201.

Moreover, the district court's application of Section 402(a)(4) is consistent with the judicial construction of the statute which preceded the present Act. In *United States* v. *Sprague*, 208 Fed. 419 (E.D.N.Y. 1913), cited and relied upon by the district court (A-736-737), defendants were criminally charged under the Pure Food and Drugs Act of 1906 with shipping adulterated oysters in interstate commerce. The adulteration alleged consisted of the presence of certain bacteria which were absorbed by the live oysters during their growth process.

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[13] *See* 40 Fed. Reg. 24168, 24169 (June 4, 1975).

Defendants moved to quash the information contending that the statutory definition of adulteration [14] was insufficient to encompass bacteria consumed by oysters in their natural functions. The Court squarely rejected that contention and held:

> A substance containing bacilli liable to cause disease to such an extent as to make it dangerous for food purposes is certainly "filthy", under the meaning of that word as generally used, and especially since the result of investigation has shown that filth or dirtiness is dangerous through the germs which it contains, and not solely because of offense to the senses. 208 Feb. at 421.

Nova Scotia argues that *Sprague* provides no support for the district court's conclusion because the section of the former statute under which it was decided has been carried over into the first clause of Section 402(a)(3) of the Act, 21 U.S.C. 342(a)(3)—adulteration of food by reason of the presence therein of a filthy, decomposed, or putrid substance—not Section 402(a)(4). However, this argument is at odds with Nova Scotia's contention that bacteria which pre-exist in waters from which fish have been taken are not filth of the kind that renders food adulterated under Section 402(a)(4).[15]

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[14] The statute, in relevant part, provided as follows:
Sec. 7. . . . an article shall be deemed to be adulterated . . .
Sixth: If it consists in whole or in part of a filthy, decomposed, or putrid animal or vegetable substance. . . .

[15] Nova Scotia's reliance on *Merck & Company, Inc.* v. *Kidd*, 242 F.2d 592 (6th Cir.), *cert. deneid*, 355 U.S. 814 (1957), to undercut the viability of *Sprague* is similarly misplaced. [Br. p. 19]. That action was a personal injury diversity case brought by a hepatitus victim against the manufacturer of blood plasma which was allegedly contaminated with the virus. Plaintiff contended

[Footnote continued on following page]

The framers of the present Act clearly had no intention of weakening the law as it existed when *Sprague* was decided. Indeed, one of the primary objectives of the 1938 Act was "to strengthen and extend the law's protection of the consumer." S. REP. No. 152, 75TH CONG., 1ST SESS. (1937). Significantly, the Act as originally proposed did not include the particular clause of Section 402(a)(4)—"whereby it may have been rendered injurious to health"—which the time-temperature-salinity requirements of the GMP regulations particularize. *See* S. 1944, 73D CONG., 1ST SESS. (1933).[16] It first appeared in the Senate Commerce Committee's report on a later version of the bill. S. REP. No. 361, 74TH CONG., 1ST SESS. (1935). Nova Scotia's argument that the term

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that the presence of the hepatitus virus rendered the plasma adulterated under Tennessee food and drug law, as consisting of a "filthy, putrid or decomposed substance" and, thus, that defendant was negligent *per se*. The parties agreed that in the absence of relevant Tennessee decisions, decisions under Section 402(a)(3) of the Federal act would control. The court went on to hold that the hepatitus virus did not constitute a filthy substance under the Tennessee statute.

In reaching its conclusion that hepatitus virus did not constitute filth, the court observed that:

> The fact that hepatitus virus is injurious to health is thus clearly irrelevant to the question of whether or not it is filthy. 242 F.2d at 595.

But the Court in *Merck* implied that if, as here, the relevant statute dealt with possible injury to health, it would have reached a contrary result. 242 F.2d at 595. This is precisely the relevant inquiry in determining whether the failure to process whitefish so as to prevent the outgrowth and toxin formation of *botulinum* bacteria constitutes an insanitary condition whereby the fish may have been rendered injurious to health and, thus, whether the GMP regulations are within the scope of Section 402(a)(4).

[16] Section 3(a)(4) of S. 1944 provided only that:

> A food shall be deemed to be adulterated—
>
> * * * * *
>
> if it has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth.

"insanitary conditions" in Section 402(a)(4) encompasses solely traditional types of readily visible filth thus fails to grasp the import of Congress' inclusion, in the Act as ultimately passed, of the second clause of Section 402(a)(4). As recognized by the trial court, Congress intended to protect consumers from contaminants of whatever nature which *may* render food injurious to their health. In construing the term, "insanitary conditions," this Court should recognize, as did Justice Douglas in a different context in *United States* v. *Urbeteit*, 335 U.S. 355, 359 (1948), that "[t]he problem is a practical one one of consumer protection, not dialectics." *See also, e.g.*, *United States* v. *Sullivan*, 332 U.S. 689, 696 (1948); *United States* v. *Bacto-Unidisk*, 394 U.S. 784, 798 (1969).

Nova Scotia's contention that FDA officials themselves have "interpreted" Section 402(a)(4) as applying only to standards of cleanliness [Br. p. 15] is frivolous. The source cited by Nova Scotia for this alleged "administrative interpretation" is an article appearing in Vol. I of the Food, Drug, Cosmetic Law Journal in 1945. Nova Scotia ignores the more recent and credible "administrative interpretations" of the proper scope of Section 402(a)(4) provided by FDA's supplemental good manufacturing practice regulations promulgated for frozen raw breaded shrimp, 21 CFR 128a, thermally processed low-acid foods packaged in hermetically sealed containers, 21 CFR 128b, cacao products and confectionary, 21 CFR 128c, and bottled water, 21 CFR 128d, and proposed for bakery goods, proposed 21 CFR 128e (See 41 Fed. Reg. 6456, February 12, 1976). These regulations, like the smoked fish GMP's, contain provisions which are intended to prevent bacterial contamination of food and are the proper source to which to turn to determine FDA's interpretation of the scope of Section 402(a)(4).[17]

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[17] Of course, if the time-temperature-salinity requirements of the smoked fish GMP's are outside the scope of Section 402(a)(4), these regulations may be beyond the statute as well.

Similarly, Nova Scotia argues [Br. p. 17] that the title of the smoked fish GMP regulations, "Current good manufacturing practice (sanitation)" (A-618), supports its contention that the regulations are properly limited to traditional filth concepts. But this ignores the preamble statement accompanying this title in the final publication of the regulations. There, the Commissioner of Food and Drugs found:

> (1) That although adequate times, temperatures, and salt concentrations have not been demonstrated for each individual species of fish presently smoked, the processing requirements of the proposed regulations are the safest now know to prevent the outgrowth and toxin formation of C. botulinum Type E; and (2) that since the public health hazard of C. botulinum Type E in smoked fish is not restricted to a single species of fish, the conditions of current good manufacturing practice for this industry should be established without further delay. (A-618).

Thus, it is clear that from the time these regulations were promulgated FDA has considered them to go beyond traditional filth notions. It is the specific time-temperature-salinity requirements of the GMP's and the reason for their existence, not the regulations' descriptive title, which determines whether they are properly within the scope of Section 402(a)(4).[18]

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[18] Nova Scotia suggests that FDA had ample authority to deal with problems of microbial contamination of smoked fish under Section 404(a) of the Act, 21 U.S.C. 344(a), which allows the FDA to control commerce in contaminated food for a temporary period of time pursuant to a permit system. Section 404(a), however, comes into play for only temporary periods *after* an emergency arises whereas the time-temperature-salinity regulations are designed to obviate any such emergency.

[Footnote continued on following page]

The time-temperature-salinity requirements of the smoked fish GMP regulations are within the scope of Section 402(a)(4) and Nova Scotia's arguments to the contrary must be rejected.

POINT II

The Time-Temperature-Salinity Requirements of The Smoked Fish GMP Regulations Are Valid.

Nova Scotia contends that the time-temperature-salinity requirements are invalid because of alleged deficiencies in the administrative record.[19] [Br. p. 24]. The

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Moreover, the regulations implementing Section 404(a), 21 CFR 90, demonstrate that the emergency permit control section of the Act is in addition to, and not in derogation of, the adulteration provision of the Act. For example, the GMP regulations for low-acid canned foods, 21 CFR 128b, were also promulgated pursuant to Sections 701(a) and 402(a)(4) of the Act and, like the smoked fish GMP regulations, are directed, in large measure, to the problem of *C. botulinum* in such food. (See 38 Fed. Reg. 2401, January 23, 1973). A failure appropriately to follow these GMP regulations may trigger application of the emergency permit control provision. The existence of the authority to issue permits under Section 404(a) of the Act—or even to promulgate GMP regulations under that section—in no way undermines FDA's authority to promulgate GMP regulations under Section 402(a)(4). As the court in *Philadelphia Television Broadcasting Co.* v. *F.C.C.*, 359 F.2d 282, 284 (D.C. Cir. 1966), observed:

> In a statutory scheme in which Congress has given an agency various bases of jurisdiction and various tools with which to protect the public interest, the agency is entitled to some leeway in choosing which jurisdictional base and which regulatory tools will be most effective in advancing the congressional objective.

See also, e.g., Mt. Mansfield Television, Inc. v. *F.C.C.*, 441 F.2d 470, 481 (2d Cir. 1971).

[19] Introduced into evidence as Defendants' Exhibit "D."

gravamen of this argument is that the agency acted improperly in relying on scientific and technical materials which had not been formally disclosed to the public. [Br. p. 27]. Moreover, their argument runs, even if such reliance was proper, the district court was incorrect in holding that the administrative record—whether taken in its entirety or excluding the allegedly undisclosed materials—fully supports the regulations. [Br. p. 42]. We submit that the district court was correct in finding that the administrative record was properly produced and that it fully supports the regulations.

A. The Administrative Record Properly Consists Of The Scientific Material Relied On By FDA In Proposing And Promulgating The GMP Regulations.

1. The Administrative Record Was Properly Produced.

As part of their discovery in this action, Nova Scotia requested that the administrative record of the smoked fish GMP regulations be produced (A-24). In response, FDA personnel secured the factual material that was considered by the agency at the time it determined to adopt the regulations.[20] This material, divided into several tabs, consisted of the following: (1) documents filed with the FDA Hearing Clerk in the rulemaking proceeding, including copies of all comments received in response to the proposed regulations [TAB A]; (2) reports submitted to FDA by researchers who were under contract with the agency to conduct studies on the incidence and hazard of *C. botulinum* type E in smoked fish, and on processing requirements which would minimize those hazards [TAB B (1)-(12)]; (3) copies of reports provided to FDA by the Bureau of Commercial Fisheries describing general guide-

[20] Affidavit of Arnold Isaac Friede (A-34).

lines for processing and sanitation controls necessary to minimize risks associated with smoked fish [TAB C (1) and (2);] (4) copies of studies prepared by FDA employees with respect to feasibility of compliance with the processing parameters later embodied in the GMP's and with respect to the market acceptability of smoked fish so produced [TAB D(1)-(4)]; (5) a copy of a summary of a meeting held by the FDA with scientists to discuss processing requirements for smoked fish [TAB E]; and, (6) copies of scientific articles,[21] dated prior to promulgation of the regulations, which deal with the incidence of *C. botulinum* type E, appropriate cooking-smoking times and temperatures, effects of salt, and storage temperatures. [TABS F(1)-(72), G(1)-(10), H(1)-(7), I, J(1)-(23), K(1) and (2) and (L)].

The FDA attorney responsible for retrieving the administrative record testified at trial that the record produced represented his attempt to trace the history of the regulation and to find all the data that were before the agency at the time (A-217). As the district court observed, the attorney, in assembling the record, attempted "to gather everything, good, bad, indifferent that was under review at the time in [sic] the regulation was adopted" (A-216). Contrary to Nova Scotia's argument [Br. p. 28], the manner in which the administrative record of the smoked fish GMP rulemaking proceeding was retrieved and produced was not unique, but, rather, consistent with the procedures commonly followed by virtually all agencies in compiling the record for review of regulations promulgated, as here, through notice-and-comment rulemaking under the APA. *See* Pederson, *Formal Records and Informal Rulemaking*, 85 Yale L. J. 38 (1975).

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[21] For a listing see Exhibit A to Friede Affidavit (A-34-48).

Nova Scotia's characterization [Br. p. 19] of the scientific material in TABS B through L of the record as "secret data" known only to FDA is totally inaccurate and, indeed, contrary to the district court's findings. As the court observed:

> [T]here is no ground for considering the material under Tabs B through L as being in the nature of *ex parte* evidence secretly acted upon to the disadvantage of the class affected by the adoption of Part 128a. In truth, the material contained under Tabs B through L comprises a reference library of the contemporary scientific work being done in the field, and to an extent, internal government views of the matter in the course of evolving a final administrative position. The internal evidence of the interdepartmental exchanges indicates that what the government was thinking about and doing was well known in the industry and to those who were actively interested in the inquiries being pursued as a result of the 1960 and 1963 poisonings, patricularly the associations of interested persons. The rest of the material was published material which was either known to or readily accessible to any expert in the field to whom the members of the class to be affected by the regulation would naturally have turned for advice and assistance. (A-769-770).

Further, the Commissioner of Food and Drugs, in his preamble to the proposed smoked fish GMP regulations, referred to FDA's consideration of extensive scientific data and the agency's willingness and desire to receive any additional data that would shed light on the problem. (A-614-615). And, meetings between FDA and Nova Scotia [22] (A-343, 622-624, 625-630) were held prior to

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[22] Indeed, defendant David Sklar testified that he personally had attended many such meetings. (A-343).

promulgation of the regulations at which the scientific bases of the GMP's were discussed.

In support of its argument that the material in TABS B through L is not properly part of the administrative record, Nova Scotia points to statements made in 1976 by FDA's chief counsel and a staff attorney to the effect that source material relied upon by the agency in rulemaking should be specifically identified. [Br. pp. 35-38]. However, this contention misconceives the import of the attorney's and chief counsel's remarks. They were referring to then proposed procedural regulations, 40 Fed. Reg. 40723 (September 3, 1975), which adopt the concept of a "closed" record on file with the FDA Hearing Clerk which would contain, *for future regulations*, the types of material contained in TABS B through L. These new self-imposed regulations may not legitimately be read as requiring FDA to have followed the *proposed* requirements in assembling the administrative record on which the smoked fish GMP's—promulgated in 1970—were based. It would be manifestly unfair to the public which is protected by the regulations, and to the Government, to evaluate the record here produced against standards and interpretations only recently enunciated. Moreover, adoption of Nova Scotia's position would discourage administrative agencies from altering their procedures to go beyond the minimum statutory requirements for fear that a court would infer from the very act of transition that a prior practice was legally defective.

Had Nova Scotia challenged the GMP regulations by way of a declaratory judgment action following their promulgation in 1970,[23] as they were entitled to do,

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[23] The district court took note of the fact that no proceedings had ever been instituted to review the regulations as adopted. (A-754).

Abbott Laboratories v. *Gardner*, 387 U.S. 136 (1967), no basis would have existed for charging a failure to comply with procedural requirements first proposed in 1975. The fact that appellants waited until 1976 to challenge the time-temperature-salinity requirements should not legitimate Nova Scotia's claim that FDA was obligated to have followed in 1969 and 1970, record keeping procedures that were not adopted by the agency until some six years later.

Nova Scotia's contention [Br. p. 39] that there is no evidence indicating that FDA considered any of the scientific data in TABS B through L is belied by examination of the documents themselves. For example, as the district court noted (A-759-60), TAB B consists of scientific studies prepared by University of Wisconsin researchers under contract to FDA. TAB D consists of reports of experiments conducted by FDA's own New York District Office. (A-760-761). And TAB E highlights FDA's consideration of all the relevant scientific data now included in the record. As digested by the district court (A-761-764), this summary of a meeting held by FDA on July 11, 1968, evinces the agency's full consideration of all data and all viewpoints. Indeed, Dr. Jack Graikowski of the Bureau of Commercial Fisheries [24] there publicly reviewed the work he had conducted on smoked fish processing parameters.[25] Accordingly, Nova Scotia's contentions that the scientific material in the record consisted of "secret data" and that the agency failed to consider the scientific data in support of the regulations are contradicted by the record itself.

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[24] The district court noted that the Bureau represented the concern of the hot-process smoked fish processors. (A-770-771).

[25] See Deft. Ex. D, TABS C(1), C(2), F(42), G(1), G(5), and L.

2. The Entire Administrative Record Satisfies the Administrative Procedure Act.

Nova Scotia's assertion that TAB A alone constitutes the proper administrative record for judicial review of the time-temperature-salinity requirements fails to take into account the type of "record" which is required in judicial review of regulations issued in accordance with the notice and comment procedure of Section 4 of the APA, 5 U.S.C. 553. Appellants have attempted to apply to this case the more stringent meaning of "record" for judicial review of agency orders and adjudications under Sections 7 and 8 of the APA, 5 U.S.C. 556, 557.[26] Thus decisions involving review of formal orders or adjudicatory hearings, such as *Ohio Bell Telephone Co.* v. *PUC*, 301 U.S. 292 (1937), quoted at length by Nova Scotia [Br. p. 29], provide no instruction as to the proper nature of the record for informal rulemaking. *See generally* K. Davis, *Administrative Law of the Seventies* §29.01-6, at 669-675 (1976).

An authoritative statement governing the appropriate composition of the administrative record for review of informal rulemaking is found in 1 CFR 305.74-4. There, the Administrative Conference of the United States recommends that:

> [T]he following are the administrative materials that should be before a court for its use in evaluating, on pre-enforcement judicial review, the factual basis for rules adopted pursuant to informal procedures prescribed in 5 U.S.C. section 553: (1)

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[26] The district court noted this distinction. It observed that: [the regulations do] not come within 5 U.S.C. 556 or 557 but rather within 5 U.S.C. 553(c), which simply requires that the agency, after considering the relevant matter presented, shall incorporate in the rules adopted a concise general statement of their basis and purpose. (A-747).

> the notice of proposed rulemaking and any documents referred to therein; (2) comments and other documents submitted by interested persons; . . . (4) *factual information not included in the foregoing that was considered by the authority responsible for promulgation of the rule or that is proffered by the agency as pertinent to the rule*; . . . and (6) the agency's concise general statement or final order and any documents referred to therein. References to the "record" or "whole record" in statutes pertaining to judicial review of rules adopted under section 553 should be construed as references to the foregoing in the absence of a legislative intent to the contrary. (Emphasis added).

The scientific materials submitted as TABS B through L of the administrative record of the smoked fish GMP regulations fall directly within the scope of (4) above because they comprise the data that was considered by FDA at the time it promulgated the regulations.[27] Although inclusion of this data is inconsistent with the concept of the record in adjudicatory proceedings, it comports fully with the requirements for a proper record in APA informal rulemaking as it stood at the time the smoked fish GMP regulations were proposed and promulgated.

If the record in informal rulemaking were restricted to the comments filed and the basis and purpose statement of the agency, as Nova Scotia suggests, much of the back-

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[27] It should be noted that all of the materials in TABS B through L predate the issuance of the regulations. (A-756). Nova Scotia's contention that these documents were created *post hoc* [Br. p. 26] is, therefore, erroneous.

ground for an agency's decision might never be part of the record. An agency is required to "give interested persons an opportunity to participate in the rulemaking through submission of written data, views, or arguments . . ." 5 U.S.C. 553(c). An agency does not, however, comment on its own proposal, nor does the APA require that it place in some previously identified "record" the information on which its decisions are made.[28]

In promulgating regulations like the smoked fish GMP's, FDA may properly rely on information of the kind included in TABS B through L of the record. As the court in *Citizens Band Assoc.* v. *United States*, 375 F.2d 4354 (9th Cir. 1967), held:

> When, as here, a statute does not require that a particular kind of rulemaking be on a record made after public hearing, the Commission is not confined to evidence presented in some formal manner. It may act not only on the basis of comments received in response to its notice of rulemaking, but also upon the basis of information available in its own files, and upon the knowledge and expertise of the agency. [Citations omitted].

Accord, Siegel v. *Atomic Energy Comm'n*, 400 F.2d 778, 786 (D.C. Cir. 1968).

In rulemaking, an agency can go beyond the "formal" record such as that compiled by the FDA Hearing Clerk in this case. If it were confined to the comments and its own proposal, it would be unable to draw upon its expertise. *Pacific Coast European Conference* v. *United States*,

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[28] Compare 5 U.S.C. 556(d), where in *formal* rulemaking the burden of proof is placed upon the proponent of the rule (normally the agency) to introduce substantial *evidence* in support of its conclusion .

350 F.2d 197, 205 (9th Cir. 1965); *cf. City of Chicago* v. *Federal Power Commission*, 458 F.2d 731, 747 (D.C. Cir. 1971), *cert. denied*, 405 U.S. 1074 (1974); *Amoco Oil* v. *E.P.A.*, 501 F.2d 722, 729 n. 10 (D.C. Cir. 1974). As the court in *Environmental Defense Fund* v. *E.P.A.*, 465 F.2d 528, 537 (D.C. Cir. 1972), observed:

> We do not demand sterile formality. In appropriate cases, if the necessary articulation for administrative action can be discerned by reference to clearly relevant sources other than a formal statement of reasons, we will make the reference. (footnote omitted).

Moreover, this Court recently held that in notice-and-comment rulemaking, "it is sufficient if the regulations be supported by evidence in the Commission's files or even its own expertise." *Consumer Union* v. *Consumer Product Safety Commission*, 491 F.2d 810, 812 (2d Cir. 1974).

In the instant case, as well, the materials in TABS B through L of the record are the scientific bases upon which FDA formulated the judgments embodied in the regulations. (A-744). They should be considered part of the record for review of the time-temperature-salinity requirements.

It is noteworthy that the materials in TABS B through L consist almost entirely of what the trial court called "neutral investigative studies" (A-759), and FDA's reliance on them in no way prejudiced Nova Scotia. (A-759). Because a showing of prejudice must be made before a court will disturb an agency's reliance on material in its files in an adjudicatory proceeding, *Market Street Ry. Co.* v. *Railroad Commission*, 324 U.S. 548, 562 (1945); *United States* v. *Pierce Auto Freight Lines, Inc.*, 327 U.S. 515, 530 (1946), it follows that such

a showing must be made in a case involving informal rulemaking. Nova Scotia was given notice of the precise time-temperature-salinity parameters proposed by FDA. Indeed, FDA responded to processor suggestions by allowing an alternative method of brining and cooking fish.[29] Nova Scotia failed to make any showing in the district court that it was prejudiced by FDA's consideration of the data in TABS B through L (A-756-758) and, for this additional reason, its argument that this material should be excluded from the record must be rejected. *Cf. City of Chicago* v. *Federal Power Commission*, 458 F.2d at 748.

B. The Administrative Record Supports the Validity of the Smoked Fish GMP Regulations.

The smoked fish GMP regulations were promulgated under Section 701(a) of the Act pursuant to the notice-and-comment procedure of Section 4(c) of the APA. In *National Nutritional Foods Ass'n* v. *Weinberger*, 512 F.2d 688 (2d Cir.), *cert. denied*, 423 U.S. 827 (1975), this Court described the standard applicable to review of such regulations:

> Since no . . . hearing was required . . . the appropriate standard for review of a regulation promulgated pursuant to the 'notice and comment procedure' has been recognized to be that specified by 5 U.S.C. § 706(2)(A), which authorizes a reviewing Court to hold unlawful and set aside agency action, findings and conclusions found to be 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.' See *National*

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[29] As noted by the district court, "the Commissioner's actions in modifying the original proposal demonstrate the openness of the proceeding". (A-769).

Nutritional Foods Assn. v. *FDA*, 504 F.2d 761, 773 n. 8 (2d Cir. 1974); *Consumer Union of United States* v. *Consumer Product Safety Commission*, 491 F.2d 810 (2d Cir. 1974). 512 F.2d at 700.

See also, e.g., Weinberger v. *Hynson, Wescott & Dunning, Inc.*, 412 U.S. 609, 622 n. 19 (1973); *Camp* v. *Pitts*, 411 U.S. 138, 140-141 (1973).

This limited standard of review takes into account the administrative agency's experience and expertise in dealing with the relevant factors, *Pre-Fab Transit Co.* v. *United States*, 306 F. Supp. 1247, 1250 (S.D. Ill. 1969), *aff'd per curiam*, 397 U.S. 40 (1970) and serves the Congressional purpose behind the Administrative Procedure Act. *Cf. Consolo* v. *F.M.C.*, 383 U.S. 607, 620 (1966). It assures that where, as in the case at bar, an agency has been delegated the task of making rules to carry out a statute's provision, "the validity of a regulation promulgated thereunder will be sustained so long as it is 'reasonably related to the purposes of the enabling legislation' . . ." *Mourning* v. *Family Publications Service, Inc.*, 411 U.S. 346, 369 (1973). *See also, e.g., Johnson's Professional Nursing Home* v. *Weinberger*, 490 F.2d 841, 844 (5th Cir. 1974).

1. The Administrative Record in its Entirety Supports the Time-Temperature-Salinity Requirements.

Nova Scotia argues (Br. pp. 45-49) that the entire record (TABS A through L) fails in three respects to support the alternative time-temperature-salinity require-

ments: (1) absense of relationship to sanitation;[30] (2) no reasonable possibility of injury to health; and (3) lack of consideration of commercial feasibility. Curiously, in making these arguments, Nova Scotia fails to rebut or even refer to the district court's extensive discussion of the entire administrative record. (A-755-771).

Nova Scotia's argument that the administrative record fails to demonstrate that a reasonable possibility of injury to health arises from preparing smoked fish in violation of the time-temperature-salinity requirements is itself without support.[31] The only stated support for this contention is the bald assertion (Br. pp. 47-48) that the FDA, in promulgating the regulations, ignored the fact that industry had abandoned vacuum packing and that no reported cases of botulism from smoked fish had occurred in the years between 1963 and 1970.

The record demonstrates, however, that the abandonment of vacuum packing was not a sufficient reason for FDA to forego promulgation of the regulations.[32] In this

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[30] This argument is, in essence, a repetition of Nova Scotia's earlier argument that the regulations are not within the scope of Section 402(a)(4). The Government's previous response need not be repeated here. *See* discussion in Point I *supra*.

[31] The existence of a reasonable possibility of injury to health is the predicate for particularizing Section 402(a)(4) through these requirements. *See Berger* v. *United States*, 200 F.2d 818, 821 (8th Cir. 1952).

[32] Although the lack of air due to vacuum packing contributes to the botulism hazard by increasing the shelf life of the product, and thus provides greater time and opportunity for outgrowth and toxin production [Deft. Ex. D, TAB F-58, p. 5], it is equally true that the absence of vacuum packing does not eliminate the problem. Studies have shown that smoked fish have an oxidation-reduction potential sufficiently low to permit the growth of anerobes, such as *C. botulinum* type E, even when the product is continuously exposed to air [Deft. Ex. D, TAB F-58, p. 4]. The

[Footnote continued on following page]

regard, the district court stated:

> The post-1963 success of the industry was certainly a cause of self-congratulation. But the Commissioner could hardly be unaware, that success begets a relaxation of vigilance, and that inspection reports could not demonstrate industry-wide uniformity of procedures. Nor could the Commissioner guarantee the maintenance of self-imposed processing standards. (A-757-758).

Furthermore, the existence of a reasonable possibility of injury to health arising from violation of the alternative time-temperature-salinity processing requirements is fully and completely documented in the record. The district court discussed this issue at length (A-739-747), noting that "[t]he controversy is solely about what time-temperature-salinity parameters are appropriate to give assurance of safety to the consuming public and the fish processors; it is not about the propriety of establishing such parameters." (A-744).

Nova Scotia's argument that the record evidences a failure to consider the commercial feasibility of complying with the regulations presumes that compliance with the regulations is not possible. Nova Soctia, however, resoundly failed at trial to establish the impossibility of compliance (A-771-774).

The evidence introduced at trial, the district court noted, "demonstrated only that the processors who testified were unable to meet the parameters without material change in their processing practices." (A-771). Indeed, the evidence showed that there were "numerous techniques

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record thus demonstrates that the elimination of vacuum packing was not sufficient reasons for FDA to forego adoption of the GMP regulations and the district court recognized as much (A-747).

that the industry had not yet exploited" (A-771) and that the processors had not attacked the problem of compliance with the "resolution and industrial ingenuity that would have been summoned if they had acted in the recognition that they would simply have to comply with the parameters of Part 128a if they were to continue in operation." (A-772). The district court properly placed the burden of compliance on the industry:

> The industry itself had faced the risk that if C. botulinum Type E was not dealt with effectively, its business would be destroyed. If the material under Tabs B through L shows anything, it shows that when Part 128a was proposed in late 1969, it was high time that some such proposal was made, no less in the industry's interest than in the public's interest in personal safety. It was for the industry to devise methods of preserving marketability within the parameters, if, as was inevitable, it was unable to bring forward adequate evidence that some other approach would serve the public interest. (A-773).

Moreover, even assuming that compliance was not possible, the district court held that:

> [I]t is not an answer to regulation to say that marketable fish could not be processed under it. If that were the case it would simply mean that smoked whitefish cannot be regarded as safe and that whitefish cannot be processed in their only marketable form without an unacceptable threat to public health. The ultimate fact appears to be that industry has not been able to come forward with alternative, safe processing means in which it has enough confidence to press them upon the Commissioner and the industry has not exhausted the search for means of living within the parameters and still preparing marketable smoked whitefish. (A-773)

Cf. United States v. *Ellis Research Laboratories*, 300 F.2d 550, 554 (7th Cir.), *cert. denied*, 370 U.S. 918 (1962). In any event, the entire record demonstrates that FDA, consistent with its paramount objective to protect the public health, fully considered the ability of industry to comply. (A-761); Deft. Ex. D, TABS C(2), D(1) through (4), G(2), G(6). The district court correctly concluded that the record in its entirety supports the time-temperature-salinity requirements.

Nova Scotia's response to the trial court's analysis grossly distorts the conclusion reached. Nova Scotia states in its brief that, "The court below concluded that the material in Tabs B through L 'added nothing of moment to what is in the formal record'." [Br. p. 49]. The court actually stated as follows:

> The expert and the industry evidence introduced at the trial is not at war with anything contained in the Tabs B through L material, and, in fact, added nothing of moment to what is in the formal record. (A-768)

Thus, contrary to Nova Scotia's suggestion, it was its own evidence, and not the material in TABS B through L, that added nothing of moment to the formal record.

2. The Material Compiled by the FDA Hearing Clerk (TAB A) Supports the Time-Temperature-Salinity Requirements.

Even assuming that this Court were to hold that the scientific data in TABS B through L are not properly considered in determining the validity of the time-temperature-salinity requirements of the GMP regulations, the materials compiled by the FDA Hearing Clerk in the rulemaking proceeding—which Nova Scotia con-

cedes are properly part of the record [Br. p. 43]—support those requirements.

Nova Scotia's argument [Br. p. 44] that the TAB A materials are insufficient because they consist largely of adverse comments filed by the smoked fish industry does not withstand analysis. Nova Scotia contrasts the TAB A materials to the administrative record before this Court in *National Nutritional Foods Ass'n* v. *Weinberger*, *supra*. It then summarily concludes, without any analysis whatever, that the TAB A materials are inadequate to support the time-temperature-salinity requirements at issue. The record in *Nutritional Foods*, consisting of some 46 folders containing 2,500 written comments and accompanying medical and scientific data, analysis and criticism, was *submitted in response to* the Commissioner's invitation pursuant to Section 4(c) of the APA. 512 F.2d at 692, 700. Nova Scotia cannot now complain that the smoked fish industry's failure to provide similarly detailed responses or, for that matter, any data showing that the time-temperature-salinity parameters embodied in the GMP's are unreasonable, requires that the regulations be invalidated. Here, as in *Nutritional Foods*, "[a]ppellants and all others concerned were given ample notice of the proposed action and an opportunity to submit documents, data and arguments". 512 F.2d at 700.

Moreover, Nova Scotia fails to focus on the issues raised in the rulemaking proceeding. As the district court observed:

> The occasion was not one at which anyone was disposed to or able to take the position that botulism was nothing to worry about, or that C. Botulinum Type E was not ubiquitous in the fresh waters from which the fish were drawn, or that salination and thermal treatment were not basic in the hot-process smoked fish industry. It is not

> even deniable that to an indeterminate extent the industry was under loose self-regulation in the same respects covered by Part 128a—that is, in the use of salination and thermal controls. The industry had regulated itself not only to make an edible product but also in the interest of protecting the customers of the processors' customers from the risk of botulism. (A-757).

Indeed, NFI, in a letter to FDA on December 23, 1970 (A-691-701), conceded [33] that the agency acted reasonably:

> The industry recognizes that all processing requirements contained in FDA's good manufacturing practice regulations must be based on public health considerations. It is also recognized that these requirements cannot be reduced simply because the industry is unable to meet them. Such requirements should, however, be as flexible as possible to afford the industry as many alternative processing parameters as can be justified based on public health considerations. (A-752).

It was precisely in response to industry comment that FDA altered its original proposal [34] to permit the alternative of cooking the fish at 150°F for 30 minutes with 5 percent salt. As the district court found:

> The Commissioner's modification of Section 128a (d)(2) to incorporate the 150°-5% alternative met the industry's most clearly expressed objection. (A-752).

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[33] The district court observed that this letter "correctly" framed the issues resolved in the rulemaking proceeding. (A-752).

[34] The regulations, as originally proposed, would have required that all fish be heated to 180°F for 30 minutes and contain 3.5 percent salt. (A-616).

This modification was based on comments received on the original proposal from, among others, NFI speaking on behalf of the 26 firms actively smoking fish.[35] (A-750). *See Automotive Parts & Accessories Ass'n* v. *Boyd*, 407 F.2d 330, 334 (D.C. Cir. 1968).

Finally, Nova Scotia has failed here, as it did in the district court, to make any showing which would "indicate that a total reconsideration of the entire matter within FDA as of November 1970 could have resulted in any different regulation than the one then adopted." (A-758). As the district court held:

> On the formal administrative record [TAB A], therefore, the action of the Commissioner in adopting Part 128a was neither arbitrary nor capricious nor an abuse of discretion nor otherwise unauthorized. (A-755).

3. The Basis And Purpose Statement of the Smoked Fish GMP Regulations Is Adequate And Sufficient.

The APA requires that an agency incorporate in rules adopted "a concise general statement of [their] basis and purpose". 5 U.S.C. 553(c). The Commissioner's preamble to the smoked fish GMP's fully complies with this mandate:

> The principal objection is that the process requirements in the proposed regulations cannot be applied to all species of fish presently being smoked

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[35] The district court observed that:
The Commissioner manifestly acted after considering the comments submitted to him, and before final adoption, he materially modified the proposal in accordance with the most important of the objections and suggestions submitted to him. (A-754).

> by the industry and that the regulations should therefore specify time-temperature requirements, as developed by research and study, on a species-by-species basis.
>
> The Commissioner finds: (1) That although adequate times, temperatures and salt concentrations have not been demonstrated for each individual species of fish presently smoked, the processing requirements of the proposed regulations are the safest now know to prevent the outgrowth and toxin formation of *C. botulinum* Type E; and (2) that since the public health hazard of *C. botulinum* Type E in smoked fish is not restricted to a single species of fish, the conditions of current good manufacturing practice for this industry should be established without further delay. [Quoted at A-748].

Nova Scotia's assertion that FDA failed to respond to comments from the industry is simply not true. As the district court noted, the Commissioner's modification of the proposed regulation "to incorporate the 150°-5% alternative met the industry's most clearly expressed objection". (A-752). This change was at the express request of NFI. Nova Scotia's comment (A-655) that the time-temperature-salinity requirements could not be applied to all species of hot-smoked fish was specifically addressed by the Commissioner. As the district court observed, no one, including Nova Scotia, ever asserted during the rulemaking proceeding that the risk of botulism poisoning was non-existent or that standards of salination and thermal treatment were not required in the industry. (A-757). Indeed, smoked fish are what they are precisely because they are heated and salted. (A-757).

In this context, the Commissioner's statement of basis and purpose is clearly adequate. It is certainly more than sufficient when measured against standards applied to agency statements contemporaneous with the GMP's. *See Automotive Parts & Accessories Ass'n* v. *Boyd*, 407 F.2d 330, 338 (D.C. Cir. 1968).[36]

Moreover, although the Commissioner's statement of basis and purpose satisfies the recent case law interpretations cited by Nova Scotia, it would be manifestly improper to judge it against requirements non-existent at the time the GMP's were promulgated in November 1970. Since then additional procedural requirements have been engrafted on agency rulemaking both by Congress and by judicial decision. This, in turn, has led to reevaluation of the function served by the agency's concise general statement of a regulation's basis and purpose. P. Verkuil, *Judicial Review of Informal Rulemaking*, 60 Va. L. R. 185, 241 (1974). This has led courts in recent cases —some of which are cited by Nova Scotia—to require that there be more factual detail in the agency's statement of basis and purpose than previously was customary. *Id.*

However, to rule retrospectively that the statement here is inadequate because it is not replete with factual detail would cast doubt on the validity of virtually all informal regulations promulgated by FDA and other agencies prior to these recent decisions. Furthermore, Nova Scotia has been on notice of the time-temperature-salinity requirements since 1970 and failed to take any action to

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[36] There, a regulation required factory installed head restraints in all new cars. The court found the following basis and purpose statement to be adequate: "This standard specifies requirements for head restraints to reduce the frequency and severity of neck injury in rear end and other collisions". 407 F.2d at 338.

challenge them. If ever the doctrine of laches should be applied to bar the retroapplication of subsequently refined case law standards, see *Abbott Laboratories* v. *Gardner*, 387 U.S. at 155, it should preclude Nova Scotia's challenge to the adequacy of the basis and purpose statement here.

4. Nova Scotia Already Has Been Accorded the Hearing It Would Receive in the Event of a Remand.

In the event that this Court were to hold that the district court erred in concluding that the administrative record—whether limited to TAB A or expanded to include TABS B through L—supports the time-temperature-salinity requirements, it would not follow that the regulations should be declared invalid. Rather, as explained by this Court in *National Nutritional Foods Ass'n* v. *Weinberger*, 512 F.2d at 703, the customary remedy would be to remand the matter to the district court with directions to conduct an *Overton*-type [37] hearing to determine whether, upon the basis of all information available to the Commissioner at the time the regulations were issued, he acted rationally in promulgating the alternative time-temperature-salinity requirements. In the event that the district court were to then conclude that the Commissioner had indeed acted rationally, the regulations would be upheld and the injunction entered would stand. However, such a remand would not be appropriate here because the district court has already conducted an *Overton*-type hearing as part of the trial of this action. (A-775-776).

At trial, the Government objected to all testimony offered by Nova Scotia in its attempt collaterally to at-

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[37] *Citizens to Preserve Overton Park, Inc.* v. *Volpe*, 401 U.S. 402 (1972).

tack the validity of the regulations *de novo.*[38] (A-193-194). This objection was asserted against the testimony of all the smoked fish processors [See, e.g., A-278] and the "taste test" panel, which were all part of Nova Scotia's attempt to establish the impossibility of complying with the regulations and producing a marketable product. The district court reserved decision on the admissibility of this testimony. [See, e.g., (A-278-279)]. The Government additionally objected to the testimony of Dr. Melvin Eklund (A-184-222, 521-602) which was offered for the twofold purpose of attempting to establish (1) that the incidence of *C. botulinum* type E was not such as to create an "insanitary condition" with respect to improperly processed whitefish, and (2) that the time-temperature-salinity requirements were based on scientific studies involving levels of *C. botulinum* type E bacteria not likely to be encountered in nature. The Government's objection to the first part of Dr. Eklund's testimony was overruled (A-523) and, although objection to the second part of his testimony was sustained, the district court permitted it to be adduced as an offer of proof. (A-552).

In concluding that the regulations were indeed valid, however, the district court considered all of the testimony presented, including Dr. Eklund's offer of proof.[39] (A-775). On this amplified record, the court held:

> Expansion of the scope of the hearing to include evidence addressed to the validity and soundness

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[38] The Government relied on *Camp* v. *Pitts*, 411 U.S. 138, 142 (1973) and *Overton Park* in support of its position that such *de novo* review is inappropriate. See Govt. Supp. Mem. in Supp. of Prelim. Inj. 13-18.

[39] Nova Scotia's contention [Br. pp. 33-34] that testimony based on the reasonableness of the test methodology employed in formulating the time-temperature-salinity parameters was "overlooked" is at odds with the district court's opinion.

> of Part 128a served the two-fold purpose of being a species of *Overton* type [*Citizens to Preserve Overton Park, Inc.* v. *Volpe*, 401 U.S. 402 (1972)] hearing and of throwing light on the question of whether there was any occasion for an *Overton* type hearing to determine whether or not the Commissioner had acted rationally. If the case is, as the Government contends, controlled by testing Part 128a against the formal record, whether limited to the Tab A material or extended to the Tabs B through L material, the conclusion must be that Part 128a is fully supported and adequately supported in the formal record. Viewing the whole record, *including all the evidence* [emphasis supplied], it is concluded (for all the evidence, on review, is seen to exclude the need for any further *Overton* type hearing), that there is no necessity for any further hearing in this Court or for a remand to the Commissioner for reconsideration in the light of matters not before him at the time the regulation was adopted. *Cf. National Nutritional Foods Ass'n* v. *Weinberger, supra*, 512 F.2d at 703-704. (A-775-776).

Thus, the remedy which would probably be utilized by this Court were it to hold the administrative record insufficient has already been accorded Nova Scotia.[40] There is no ground, therefore, for disturbing the district court's conclusion that the time-temperature-salinity require-

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[40] Nova Scotia was permitted, for example, to adduce evidence as to what the administrative record ought properly to consist of. See (A-259-260). This is precisely the kind of hearing envisioned by the Court in *Overton Park*, 401 U.S. at 419-420, and granted to the *Nutritional Foods* plaintiffs when that case was remanded to the district court for an *Overton* hearing. See *National Nutritional Foods Ass'n* v. *Mathews*, 418 F. Supp. 394 (S.D.N.Y. 1976).

ments are valid and that "nothing has been brought forward either during the hearing in the present case nor, so far as counsel has surfaced it, in any other area, to indicate that a total reconsideration of the matter within FDA as of November 1970 could have resulted in any different regulation than the one adopted." (A-758).

POINT III

The Time-Temperature-Salinity Requirements of the Smoked Fish GMP Regulations Are Binding; Injunctive Relief is Fully Warranted.

A. The Circumstances Surrounding Promulgation of the Smoked Fish GMP Regulations Do Not Cast Doubt on Their Effect.

The district court, relying on this Court's decision in *Nutritional Foods*, rejected Nova Scotia's argument that the time-temperature-salinity requirements were not binding:[41]

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[41] In *National Nutritional Foods Ass'n* v. *Weinberger, supra*, this court rejected the argument that Section 701(a) of the Act was meant only to grant FDA authority to issue interpretive, non-binding guidelines, rather than authoritative regulations particularizing statutory requirements.

> "Whatever doubts might have been entertained regarding the FDA's power under § 701(a) to promulgate binding regulations were dispelled by the Supreme Court's recent decisions in *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 93 S.Ct. 2469, 37 L.Ed. 2d 207 (1973), and its companion cases, *Ciba Corp.* v. *Weinberger*, 412 U.S. 640, 93 S.Ct. 2495, 37 L.Ed. 2d 230 (1973); *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 93 S.Ct. 2488, 37 L.Ed. 2d 235 (1973); *USV Pharmaceutical Corp.* v. *Weinberger*, 412 U.S. 655, 93 S.Ct. 2498, 37 L.Ed. 2d 244 (1973). Those decisions interpreted § 701(a) as giving FDA the power to promulgate substantive regula-

[Footnote continued on following page]

> So far as the form and language of Part 128a are concerned, they leave no room whatever for the argument that they were not intended to be "substantive" and coercive if it was lawful for them to have that effect. (A-739).

Conceding the viability of the holding in *Nutritional Foods*, and thus the soundness of the district court's conclusion, Nova Scotia nonetheless argues [Br. pp. 53-55] that given the circumstances surrounding the proposal and adoption of the time-temperature-salinity requirements, they should be treated as interpretive only. It suggests that this should be so because it believed the regulations to be mere guidelines.[42]

But, such an impression in 1970 was on shaky ground, at best, because of the Supreme Court's decision three years earlier in *Abbott Laboratories* v. *Gardner, supra.* There, drug manufacturers brought a declaratory judgment action alleging that FDA exceeded its authority in promulgating regulations under Section 701(a) which established certain labeling and advertising requirements for prescription drugs. In the face of FDA's argument that such pre-enforcement review was improper, the Court held that the regulations constituted "final agency action" and that judicial review in a district court was therefore proper.

The Supreme Court in *Abbott* concluded that the regulations there were subject to pre-enforcement judicial review *precisely* because they were not merely formal

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> tions having the binding force of law rather than mere 'interpretive' statements enforceable only on a case-by-case basis through plenary suits against those refusing to comply." 512 F.2d at 696-697.

[42] Their belief may have been founded on the advice of counsel (A-455) which, in retrospect, was ill-conceived.

expressions of agency opinion but instead had the status of law. As the Court observed:

> Thus, if within the Commissioner's authority, they [regulations issued under Section 701(a)] have the status of law and violations of them carry heavy criminal and civil sanctions. 387 U.S. at 151-152.

Nova Scotia was surely on notice, at the time the GMP regulations were promulgated, that the agency regarded them as binding.[43] Moreover, it failed to mount a judicial challenge to the regulations in the six years between their promulgation and their enforcement in this action. The basis for their asserted belief that the regulations were not binding was eroded in those intervening years by such decisions as *Ciba-Geigy Corp.* v. *Richardson*, 446 F.2d at 468, and the *Hynson* group of cases decided by the Supreme Court in 1973, as well as the *Nutritional Foods* decision issued more than one year prior to the institution of this action.

Further, Nova Scotia's argument that circumstances surrounding promulgation of the regulations require that they be accorded interpretive effect only, totally misses the point. Although the Government disagrees with Nova Scotia's characterization of the events outlined, they are at most relevant on the question of whether the regulations are valid and not on the question of whether, if valid, they are binding. As the district court observed, "the regulations are binding *if it was lawful for them to*

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[43] Nova Scotia's contention [Br. p. 54] that it had no advance warning that GMP regulations would even be proposed is directly contrary to the 1967 article it cites in support of its belief that the regulations would not be binding. See Barnard, *Good Manufacturing Practice Regulations in the Food Industry*, Food, Drug, Cosmetic L.J. (Sept. 1967). Moreover, as the district court observed, what FDA was doing and thinking about with respect to these regulations was well-known to industry. (A-769-770).

have that effect." (A-739) (Emphasis supplied). The Government submits that it is indeed lawful for the regulations to have that effect. The regulations validly particularize requirements under Section 402(a)(4) of the Act. The district court evaluated all of Nova Scotia's evidence on the circumstances surrounding promulgation of the regulations and rejected it as insufficient to invalidate the regulations. Nova Scotia makes no showing that this conclusion was clearly erroneous.

B. Smoked Fish Prepared in Violation of the Time-Temperature-Salinity Requirements of the Smoked Fish GMP Regulations Are Adulterated Within the Meaning of Section 402(a)(4) of the Act.

Nova Scotia maintains that Section 302(a) of the Act, 21 U.S.C. 332(a), does not authorize the granting of injunctive relief on the basis of a showing that an FDA regulation has been violated. [Br. pp. 55-60]. This argument is based on its reading of Section 301(k) of the Act, 21 U.S.C. 331(k), which the Government will readily concede, nowhere states, *in haec verba*, that violation of an FDA regulation is a prohibited act which may be enjoined under Section 302(a).[44]

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[44] As previously noted, *supra*, pp. 2-3 and fn. 4, the complaint alleged that Nova Scotia violated Section 301(k) as a result of producing smoked fish which were adulterated under Section 402(a)(4) because they were prepared in violation of regulations particularizing processing requirements which assure that such fish may not have been rendered injurious to health. Nova Scotia suggests [Br. p. 56] that its violation of the smoked fish GMP's does not constitute "the doing" of any act which results in the adulteration of food but, at most, was merely an omission and, therefore, not prohibted by Section 301(k). But, Nova Scotia processes smoked fish under conditions which do not meet the requirements of the regulations and it is this "affirmative act" which results in the adulteration of the fish.

But this argument misses the mark. If the time-temperature-salinity requirements validly particularize Section 402(a)(4) and if they are binding, then the Government's proof of their violation was a sufficient predicate for the injunction issued by the district court. *See United States* v. *Boyd*, 491 F.2d 1163 (9th Cir. 1973).[45] In its *Nutritional Foods* decision, this Court recognized that in cases involving binding regulations, proof of violation of those regulations was sufficient to warrant relief under the Act. As the Court noted:

> In such cases a court in an enforcement proceeding will in any event be forced to develop a considerable factual record to determine whether there has been a violation of the regulation. 512 F.2d at 696.

Thus, in proving that Nova Scotia violated the valid and binding time-temperature-salinity requirements, the Government sustained its burden.[46]

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[45]Nova Scotia's argument [Br. p. 6] that the Government failed to test the whitefish collected at its plant for the presence of *C. botulinum* type E toxin suffers from this same defect in logic. Moreover, even assuming that proof of violation of the GMP's was insufficient standing alone, proof of adulteration under Section 402(a)(4) does not require proof of the actual presence of an adulterant. *Berger* v. *United States*, *supra*, note 31,, 200 F.2d at 821; *United States* v. *Wiesenfeld Wharehouse Co.*, 376 U.S. 86 (1964); *United States* v. *Hammond Milling Co.*, 413 F.2d 608 (5th Cir.), *cert. denied*, 3. U.S. 1002 (1969).; *United States* v. *Golden Grain Macaroni Co.*, 209 F.2d 166 (9th Cir. 1953). Rather, it requires only proof that food was prepared, packed, or held under insanitary conditions whereby it *may* have been rendered injurious to health.

[46] Interestingly, in arguing that more than proof of a violation of the GMP's was required, appellants rely [Br. pp. 58-59] on a 1969 article by William Cody, *Authoritative Effect of FDA Regulations*, 24 Food, Drug Cosmetic L.J. (1969), cited and rejected in *Nutritional Foods*. 512 F.2d at 696.

Nova Scotia cites [Br. p. 58] the decision in *United States* v. *Everett Fisheries*, No. 72-CR-109 (W.D. Wisc. Dec. 31, 1975) for the proposition that the Government here was required to prove more than that the time-temperature-salinity requirements were violated in order to sustain its claim for injunctive relief. Unlike this action, *Everett* was a criminal prosecution in which the district court, in preliminary motion proceedings, ruled that violation of the smoked fish GMP's did not automatically establish the criminal violation there alleged. The court's opinion indicates, however, that the Government did not take a consistent position in that case. Although the Government argued that violation of the regulations was sufficient to establish the adulteration alleged, following the court's contrary preliminary ruling on this issue, the Government introduced testimonial evidence directly to support the allegation of a violation of the underlying statutory provision. Contrary to the instant action, it is clear that in *Everett* the Government did not regard the allegation of adulteration as resting solely on a violation of the regulations. Moreover, the court waited more than two years after trial before entering its verdict, and the "Opinion and Order" ignored the *Hynson* group of cases decided by the Supreme Court in 1973 and this Court's decision in *Nutritional Foods*. Such circumstances undermine whatever precedential value *Everett* might otherwise have had.[47]

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[47] Nova Scotia relies on *United States* v. *Lord-Mott Co.*, 57 F. Supp. 128 (D. Md. 1944), for the proposition that more than proof of a violation of the time-temperature-salinity requirements was necessary here. That case held that FDA regulations promulgated under the formal rulemaking procedures in Section 701(e) of the Act, 21 U.S.C. 371(e), and subject to statutory review in a Court of Appeals under Section 701(f), 21 U.S.C. 371(f), were nonetheless subject to *de novo* review in the district court in an enforcement proceeding. *Lord-Mott*, however,

[Footnote continued on following page]

The time-temperature-salinity requirements of the smoked fish GMP regulations validly particularize Section 402(a)(4) and their violation constitutes food adulteration under the statute. Accordingly, the district court correctly held that defendants had committed an act prohibited by Section 301(k) which was sufficient to warrant injunctive relief under Section 302(a).

POINT IV

The District Court Properly Exercised Its Discretion In Granting Injunctive Relief Against Nova Scotia.

Nova Scotia's contention that the district court's injunction is harsh and oppressive collides with the very purpose and intent of the Act. This Court adheres to the well-established view that the Act is intended to safeguard the public health and must therefore be applied broadly in order to effect its remedial purposes. *United States* v. *Diapulse Corporation of America*, 457 F.2d 25, 27-28 (2d Cir. 1972) ("The reach of the Act is broad and the provisions, touching the public interest in a direct way, are to be given a liberal construction.")

Although Nova Scotia suggests [Br. p. 60] that injunctive relief should not have been granted even though it may have violated the smoked fish GMP's, this Court has long followed the rule that where an injunction is authorized by statute, it is enough if the statutory con-

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was decided prior to the passage of the APA, was subsequently rejected, *United States* v. *Bodine Produce Co.*, 206 F. Supp. 201 (D. Ariz. 1962), and is not seriously urged as a correct statement of the current law. See S. McNamara, *The New Age of FDA Rule-Making*, 31 Food, Drug, Cosmetic L.J. 393, 394 fn. 11 (1976).

ditions are satisfied. *United States* v. *Diapulse Corporation of America, supra; Securities and Exchange Commission* v. *Management Dynamics, Inc.*, 515 F.2d 801, 808-809 (2d Cir. 1975); *Henderson* v. *Burd*, 133 F.2d 515 (2d Cir. 1943); *United States* v. *Adler's Creamery, Inc.*, 110 F.2d 482 (2d Cir.), *cert. denied*, 311 U.S. 657 (1940). The court's discretion is to be exercised in light of the objectives of the statute. *United States* v. *W. T. Grant Co.*, 345 U.S. 629 (1953); *Hecht Co.* v. *Bowles*, 321 U.S. 321, 331 (1944).

The granting of statutory injunctive relief is within the sound discretion of the district court, and a strong showing of abuse must be made to reverse it. *United States* v. *Diapulse Corporation of America, supra*, 457 F.2d at 28-29. Nova Scotia has made no showing that the district court abused its discretion in framing the relief it granted in the injunction entered, particularly in light of that court's finding that Nova Scotia made no claim of compliance with the regulations. (A-729).[48]

Nova Scotia's further contention that there is no danger to health from smoked whitefish not prepared in accordance with the requirements of the GMP's [Br. p. 60], is at odds with the very reason for the promulgation of the regulations in the first instance. Moreover, the degree of potential harm to the public from the prohibited activity is not a critical factor in determining the propriety of injunctive relief. As this Court held in *United States* v. *Diapulse Corporation of America*, 457 F.2d at 28, "[T]he passage of the statute is, in a sense, an implied finding that violations will harm the public, and ought, if necessary, be restrained. . . . [N]o specific or immediate showing of the

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[48] The district court evidenced its exercise of discretion by refusing to grant injunctive relief covering all GMP violations and limiting the relief granted solely to Nova Scotia's violation of the time-temperature-salinity requirements. (A-774).

precise way in which violation of the law will result in public harm is required." (citations omitted).

Similarly, Nova Scotia's contention [Br. p. 62] that the injunction entered would destroy the whitefish business is without merit. Not only is this assertion contrary to the trial court's findings with respect to Nova Scotia's alleged inability to comply with the regulations and produce a marketable product (A-771-773), it runs counter to the position of this court that an aggrieved party cannot ". . . complain that the injunction is impermissible because it will put him out of business. He can have no vested interest in a business activity found to be illegal. It has long been settled that the [Food and Drug] Act itself is a constitutional exercise of the commerce power". *United States* v. *Diapulse Corporation of America*, 457 F.2d at 29. (citations omitted).

Nova Scotia's selective enforcement argument is also without merit. [Br. 65-67]. A violation of law by others is of no consequence in the action against the defendants before the court. *Oyler* v. *Bowles*, 368 U.S. 448, 456 (1962); *Woodbury* v. *McKinnon*, 447 F.2d 839, 845-6 (5th Cir. 1971). Under Section 306 of the Act, 21 U.S.C. 336, FDA is not required to prosecute every violation that comes to its attention. *United States* v. *Thriftimart, Inc.*, 429 F.2d 1006 (9th Cir.), *cert. denied*, 400 U.S. 926 (1970); *United States* v. *449 Cases . . . Tomato Paste*, 212 F.2d 567, 572 (2d Cir. 1954). Nor is Nova Scotia's characterization [Br. p. 67] of this action as "spot enforcement" appropriate. This Court rejected a contention identical to that advanced by Nova Scotia in *Ger-Ro-Mar, Inc.* v. *Federal Trade Commission*, 518 F.2d 33 (2d Cir. 1975). Relying on the Supreme Court's decisions in *FTC* v. *Universal Rundle Corp.*, 387 U.S. 244 (1967); *Moog Industries, Inc.* v. *FTC*, 355 U.S. 411 (1958), and this Court's own decision in *Marco Sales Co.* v. *FTC*, 453 F.2d 1 (2d

Cir. 1971), this Court held that "while petitioners may be unfortunate in being the target of the Commission with respect to the selling practices in question, the Commission is under no obligation to start simultaneous suits against all alleged offenders." 518 F.2d at 35.

This same reasoning applies in the instant action. Whether or not the practice complained of is industry wide [49] has no bearing on the propriety of injunctive relief against Nova Scotia. The district court was well within its discretion in granting the injunctive relief prior to the imposition of similar restraints upon Nova Scotia's competitors.

Nova Scotia's litany of equitable claims, taken alone or in the aggregate, in no way establishes that the injunctive relief granted by the district court was inappropriate, unwarranted or otherwise an abuse of discretion.[50]

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[49] Nova Scotia suggests [Br. p. 65] that because industry is engaged in research on alternatives to the present regulations, the district court should have delayed the entry of judgment. Although the Government welcomes this development, it in no way affects the propriety of the injunctive relief entered. As the district court noted, the GMP's survive "under ambulatory review as the literature in the field opens up new possibilities of analysis of the botulism risk or new means of coping with the spore formation and toxin production of C. botulinum Type E." (A-776).

[50] Nova Scotia also contends that it is entitled to equitable consideration and a delay of the injunctive relief entered because the FDA has not yet acted on a petition for permission to use sodium nitrite in the processing of whitefish [Br. pp. 63-65]. (The nitrite petition was submitted by the National Marine Fisheries Service, formerly the Bureau of Commercial Fisheries). However, the nitrite petition is a matter not within the district court's jurisdiction. Exclusive jurisdiction for review of FDA's action in approving or refusing to approve that petition lies in

[Footnote continued on following page]

CONCLUSION

On the basis of the foregoing, it is respectfully submitted that the judgment appealed from should be affirmed.

Dated: Brooklyn, New York
January 31, 1977

Respectfully submitted,

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the U.S. Courts of Appeal pursuant to 21 U.S.C. 348(g) . While Nova Scotia points out [Br. p. 64] that the statute is silent as to an aggrieved party's rights when the Secretary fails to act on a food additive petition, the district court noted that the industry could seek to treat non-action in the nitrite matter as an unlawful withholding or an unreasonable delay of administrative action which could be corrected by an appropriate court under 5 U.S.C. 704, 706(1). Moreover, the district court here also held that FDA's failure to act on the nitrite petition did not furnish a ground for attacking adoption of the GMP's. "[T]he two matters", noted the district court, "are distinct in both time and substance'. (A-754-755).

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Joanne Bracco being duly sworn, deposes and says that he is employed in the office of the United States Attorney for the Eastern District of New York.

That on the 3rd day of February 1977 he served a copy of the within

BRIEF FOR APPELLEE

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and deponent further says that he sealed the said envelope and placed the same in the mail chute drop for mailing in the United States Court House, 225 Cadman Plaza East, Borough of Brooklyn, County of Kings, City of New York.

Joanne Bracco

Sworn to before me this
3rd day of February 1977

Carolyn N. Johnson

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Qual[illegible]
Term expires March 30, 1977